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SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
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December 10, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

Pursuant to Case Management Order No. 12 (Dkt. 185), as modified by subsequent email correspondence with the Court, the Manufacturer Defendants submit this letter brief setting forth their response to Plaintiffs' opening brief on outstanding discovery disputes.[1] Defendants believe relatively few true disputes remain with respect to the Rule 34 Requests for Production of Documents. The parties have engaged in extensive meet and confers, and Defendants stand ready to search their agreed custodial and non-custodial files and produce responsive documents, subject to their remaining objections and subject to the Court's November 25, 2019 Order and oral rulings from the bench on November 20, 2019. However, Defendants' agreement that there are no current disputes about certain requests does not mean that Defendants agree with the scope of the requests as currently written. Many of Plaintiffs' requests, even as amended, remain facially overbroad, vague, or overly burdensome. The Manufacturer Defendants have clarified the scope of their intended productions through their amended objections and through the various meet and confers and, in many instances, Plaintiffs do not raise disputes in response to the positions that the

[1] The positions expressed in this letter are those of the Manufacturer Defendants. For that reason, references to "Defendants" throughout this letter brief refer to the Manufacturer Defendants only.

Defendants have taken. With respect to the areas identified by Plaintiffs in their opening brief, Defendants respond as follows:

I. Outstanding Disputes Related to Plaintiffs' Document Requests

1. Corporate Organization & Custodians (Request Nos. 1-4)

Plaintiffs' December 5, 2019 letter mischaracterizes the understanding between the parties with respect to these requests. As part of the meet and confer process, Defendants have agreed to produce, and in some cases already have produced, organizational charts and information regarding the relationship between various entities. The only pending dispute with respect to these requests relates to Plaintiffs' request for information regarding "all members of the Board of Directors" and "all persons or entities which owned 5% or more of defendant's common stock." Plaintiffs have failed to articulate any basis for why this information is relevant to any parties' claims or defenses in this case. Additionally, much of this information is publicly available. Defendants have agreed to produce organizational charts reflecting board membership to the extent such charts exist, however, Defendants will not be producing information responsive to Request 2(c).

2. Policies and Procedures (Request No. 5)

Defendants agree that disputes with respect to this category were resolved by the Court's macro discovery rulings and the parties' discussions during meet and confers.

3. Agreements (Requests Nos. 6-9)

As Plaintiffs' letter states, the parties have no current pending disputes with respect to these requests. During the meet and confer process, the parties have reached an agreement that information responsive to these requests will be produced with the understanding that it will be limited to relevant documents (i.e. agreements related to testing for contamination will be produced, while agreements relating to unrelated testing will be withheld). The parties will work in good faith to ensure Plaintiffs receive the information they need, while protecting the rights of Defendants.

4. Intra-Defendant Communications (Request No. 10)

The parties have no pending disputes with this request. Defendants will produce responsive intra-defendant communications about valsartan and its ingredients within the specific topic areas identified by Plaintiffs and within the scope of discovery as ordered by the Court.

5. ANDA and DMF (Request Nos. 11-15)

First, Defendants' objections to these requests to the extent they are duplicative of the Core Discovery production are meaningful and not simply "boilerplate." These objections state that all of the ANDAs and DMFs in possession of the Manufacturer Defendants for products sold in the United States have already been produced, and Defendants should not be required to re-produce

these materials. Indeed, Plaintiffs' counsel acknowledged during the meet-and-confer process that documents already within their possession are beyond the scope of discovery. Furthermore, where Defendants have objected that certain documents are not in their possession, custody, or control, the requests as drafted ask the finished dose manufacturers to produce DMFs, which such Defendants do not maintain in the ordinary course of business. These documents are maintained and have been produced by the API manufacturers. Again, this is not a boilerplate objection, but rather an attempt by Defendants to explain what they will and will not be able to produce in response to these requests.

Second, Defendants' objection to the production of withdrawn, unapproved, or tentatively approved ANDAs is supported by the Court's November 25, 2019 Order and the Court's ruling as announced from the bench on November 20, 2019. These ANDAs relate to products which were never sold in the United States and were not and could not have been purchased or used by any of the Plaintiffs. Plaintiffs misrepresent the nature of Defendants' objection. Defendants are not limiting the production of ANDAs to only those that relate to recalled product – indeed, as Plaintiffs note, Aurolife has agreed to produce ANDA documents for a VCD which was not subject to the recall. Moreover, the Teva Defendants produced ANDA file 077530, which was also not subject to a recall since all product produced under that ANDA had already expired by July 2018. With respect to footnote 8 on page 13 of Plaintiffs' brief, Plaintiffs claim that they require Prinston's unapproved ANDA for valsartan nebivolol because "nowhere in the DMF files for ZHP's Valsartan API process is there any reference to this particular ANDA application," which makes Plaintiffs suspect that ZHP may be hiding some other unproduced DMF. Dkt. 311 at 13 n.8. That factual statement is flatly incorrect. Prinston has produced a letter of authorization dated January 10, 2017, that authorizes Prinston "to incorporate by reference information regarding the entire DMF #23491 into any ANDA filed by Prinston Pharmaceutical Inc." PRINSTON00008974. Prinston filed the ANDA application for valsartan nebivolol in June 2017 shortly after receiving this authorization. This ANDA is still under review with the FDA, and thus no products manufactured under that ANDA have been sold into the United States.

The "nexus" on which Defendants rely is sales to the United States, not whether the product was recalled. The Manufacturer Defendants have followed the Court's order to produce documents which relate to any product sold in the United States, whether or not such product was recalled. However, as detailed in Defendants' opening brief, products which were never marketed or sold in the United States are outside the scope of discovery as defined by the Court, and any legitimate bases for which Plaintiffs might seek production of these documents are already covered by the Court's order. Dkt. 312 at 32-33.

6. Document Retention/Destruction Policies (Request No. 16)

Defendants object to production of their document retention policies because, as the Court stated explicitly from the bench on November 20, 2019, there is no evidence of spoliation. 11/20/2019 Tr. of Oral Ruling at 17:25-18:2 ("The Court does not find that plaintiffs have as yet made a case that spoliation occurred in this case."). Discovery about a party's document retention policies is not relevant to a claim or defense. *See, e.g.*, *India Brewing, Inc. v. Miller Brewing Co.*,

237 F.R.D. 190, 192 (E.D. Wis. 2006) (denying plaintiff's motion to compel production of a document retention policy on the ground that it is not relevant to a claim or defense). Production of Defendants' document retention policies constitutes "discovery on discovery," which the Court has specifically stated it wants to avoid in this already sprawling litigation. *See, e.g.*, *Martin v. Allstate Ins. Co.*, 292 F.R.D. 361, 363-64 (N.D. Tex. 2013) (denying request for 30(b)(6) deposition on similar topics as irrelevant and overbroad); and *Cunningham v. Std. Fire Ins. Co.*, No. 07-cv-02538, 2008 WL 2668301, at *5 (D. Colo. July 1, 2008) (granting motion for protective order preventing the deposition of a witness on the storage and preservation of backup e-mails as not relevant to the claims). Courts "faced with discovery disputes regarding requests for information on document storage and retention have found that these requests are impermissible." *Alley v. MTD Products, Inc.*, Case No. 3:17-cv-3, 2018 WL 4689112 at *2 (W.D. Pa. Sep. 28, 2018) (attached as Exhibit A); *see Ford Motor Co. v. Edgewood Properties, Inc.*, 257 F.R.D. 418, 426-28 (D. N.J. 2009) (holding that a document request seeking information on Ford's document collection and retention system was impermissible without a showing of bad faith).

The cases cited by Plaintiffs do not support their argument that document retention policies are always relevant and discoverable. The *In re Takata Airbags Products Liability Litigation* case cited by Plaintiffs concluded that "document retention policies *may* be relevant under Rule 26 in appropriate circumstances." *See* MDL No. 2599, 2017 WL 8812734, at *5 (S.D. Fla. July 5, 2017). The Court in *Takata* acknowledged that courts had reached differing conclusions on the discoverability of retention policies and ordered production of the defendants' document retention policies after the parties had engaged in document production and identified gaps in the produced records. *Id.* at *6. The Court specifically concluded that these policies were relevant "because the Honda Defendants have represented that certain categories of evidence are unavailable." *Id.* Defendants do not dispute that document retention policies may be relevant in certain circumstances. But no such predicate for unfettered discovery into Defendants' document retention policies exists in this case.

Plaintiffs repeat the same allegations which the Court has already found insufficient to constitute spoliation. Any discovery into document retention policies must be accompanied by more than these generic statements about activity allegedly occurring long before litigation was reasonably anticipated. Discrete, Defendant-specific justifications establishing the relevance of document retention policies to the claims or defenses in this litigation must be required.[2]

7. Manufacturing (Request Nos. 19-29)

In their macro discovery briefing and at the November 20th arguments, Plaintiffs argued for expansive relevant time periods based on their supposed need for documents related to the research

[2] Notably, many Defendants offered information on their document retention policies during the course of the mandatory, in-person ESI meetings ordered by the Court. Plaintiffs have been made aware of the general nature of these policies but have not demonstrated any need for "discovery on discovery" into the policies themselves.

and development process for valsartan, including for manufacturing processes for valsartan that was never sold into the United States. *See* Dkt. 296 at 27-28; 11/20/19 Tr. at 98:14-99:15. The Court denied this request, stating that Plaintiffs could seek documents predating the relevant time periods at a later date by showing cause why "discrete, and identifiable categories of documents or individual documents" are necessary. 11/20/19 Tr. of Oral Ruling at 23:14-16; *see also* Macro Discovery Order, Dkt. 303 at ¶ 10. Plaintiffs still fail to meet this standard, and their request for earlier documents should be denied for the same reasons underlying the Court's macro discovery ruling.

To start, Plaintiffs have not identified "discrete and identifiable" documents. They request, for example, ***all*** "change request reports and/or analyses regarding ***any*** proposed manufacturing change," and "[r]isk assessments regarding ***any*** proposed manufacturing process or change." Dkt. 311-5, Exhibit 4 (email from Plaintiffs requesting exception to relevant time period) (emphasis added). As the Manufacturer Defendants have explained, the valsartan manufacturing processes are complex and involve many steps—in the case of ZHP, over 45 steps. Similarly, Plaintiffs do not limit their requests to particular types of risks, such as the risk of nitrosamine formation. Plaintiffs took the position on November 20th that they lack sufficient information to identify the particular aspects of the manufacturing processes that are relevant to the formation of the alleged impurities at issue. That remains true today. As shown by Plaintiffs' broad requests, they are still unable to identify what discrete documents they hypothetically need pre-dating the relevant time periods.[3]

In addition, Plaintiffs have not—and cannot—show good cause for their requests at this time. These are the same types of documents that Plaintiffs requested during macro discovery briefing. *See* Dkt. 296 at 28-29 (seeking risk assessments and other research and development documents predating 2010 from ZHP). The Court denied that request on November 20th, and nothing has changed since then. Before formal discovery begins, it remains purely hypothetical that Plaintiffs require any documents pre-dating the relevant time periods. Plaintiffs' request for these documents should therefore be denied unless and until they can explain in writing why there is a genuine need for specific older documents, sufficient to allow Defendants to evaluate the request and determine if the parties need to involve the Court.

8. Bioequivalence (Request Nos. 30-34)

Defendants do not believe any dispute remains with respect to this section. Defendants have agreed to produce bioequivalence testing in accordance with the Court's ruling as announced from the bench on November 20, 2019. Through their amended objections and during meet and confers, Defendants have indicated that they will not be producing documentation of patent litigation in

[3] Plaintiffs' other two requests are similarly overbroad. They request all out-of-specification, out-of-trend, and deviation investigation reports regarding lab scale development, without any limitation to the type of specification, trend, or deviation at issue and without regard to whether the document has any bearing on the risk of nitrosamine formation or other genotoxic impurities. *See* Dkt. 311-5, Exhibit 4.

response to Request No. 34 for three reasons. First, patent litigation is not relevant to any of Plaintiffs' claims. Bioequivalence is a determination made by the FDA during the approval of ANDA applications, not by courts during patent litigation. Plaintiffs have offered no explanation for how documents related to intellectual property claims will help them "understand whether Defendants complied with their duty of sameness." Plaintiffs' Appendix A, Dkt. 311-1 at 8. Second, patent litigation documents are likely to be publicly available via the judicial PACER system because these cases involve claims over which the federal courts have exclusive jurisdiction. Third, non-public documents concerning patent litigations raise myriad concerns related to attorney-client privilege and work product. In their letter brief, Plaintiffs do not dispute the Manufacturer Defendants' position on the irrelevance of these documents. *See* Dkt. 311 at 21-22.

9. Testing (Requests Nos. 35-43)

On December 6th, Plaintiffs and ZHP had a productive meet and confer in which ZHP explained how to identify the types of testing performed on valsartan and valsartan API in the ANDAs and DMFs that the Manufacturer Defendants produced in core discovery. Mylan provided similar information in correspondence served December 9. As Defendants have explained, the FDA requires that ANDAs and DMFs contain documents that list and describe testing. These documents must be organized into specific "modules." For example, ANDA module 3.2.P.5.1 "[c]ontains the specifications for the drug product," *i.e.* valsartan, "includ[ing] the tests, acceptance criteria, and references to methods in a tabular format." *ANDA Submissions – Content and Format Guidance for Industry*, at 24 (June 2019).[4] ZHP explained to Plaintiffs that its recent letter complied with the Court's order to "identify the types and purposes of the tests done on Valsartan API and Valsartan," Dkt. 303 ¶ 8, by citing to these standard modules in the ANDAs and DMFs that Prinston produced during core discovery. ZHP's letter thus was not a "hide-the-ball response," Dkt. 311 at 23, but was meant to identify for Plaintiffs the complete list of testing for their experts to review. Although Plaintiffs would prefer that the Manufacturer Defendants provide "a simple list in letter format," Dkt. 311 at 24, that is simply not realistic given the numerous types of testing performed on the various raw materials, intermediates, and finished products.[5] During this meet and confer, Plaintiffs indicated that they now understood the documents cited in ZHP's letter and had shared them with their experts.

Discovery into testing should be limited to the types of testing that the Court has already determined are relevant: HPLC and GC chromatography for impurities, including as a part of stability testing; bioequivalence testing; and residual solvents testing. *See* Dkt. 290 at 13-15

[4] Accessible at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/anda-submissions-content-and-format-abbreviated-new-drug-applications. Similar tables identifying the tests performed on excipients and on the drug product (*i.e.* valsartan API) are contained in modules 3.2.S.2.3, 3.2.S.4.1, and 3.2.P.4.1. *See id.* at 16-17, 23.

[5] Furthermore, a summary authored by counsel is less useful for Plaintiffs' experts than the technical documents themselves.

(Manufacturer Defendants' macro discovery brief explaining HPLC and GC are only test methods capable of identifying nitrosamines); Dkt. 303 ¶ 8 (limiting discovery to "test[ing] that could identify the presence of nitrosamine contamination, [and] other carcinogens or [genotoxic] impurities, or residual solvents"); 11/20/19 Tr. of Oral Ruling at 22:12-17 (finding bioequivalence testing relevant to economic loss claims). During the December 6th meet and confer, Plaintiffs appeared to acknowledge that this is the scope of testing relevant to their allegations but stated that their experts were currently reviewing the core discovery documents.

10. Nitrosamines and Contamination (Request Nos. 44-50)

The Court's order requires the Manufacturer Defendants to produce test results showing nitrosamines, other genotoxic impurities, and other carcinogens. *See* Dkt. 303 ¶ 8. The Court's order is consistent with Plaintiffs' current request for "documents regarding other nitrosamine impurities," *i.e.*, alleged contaminants other than NDMA and NDEA. The Manufacturer Defendants therefore do not believe there is a current dispute about the scope of discoverable alleged impurities.

11. Regulatory Correspondence and Documents (Request Nos. 51-64)

a) Correspondence with Foreign Regulatory Agencies Regarding "Potential Nitrosamine Contamination"

The Court's order requires production of communications with foreign regulatory agencies "regarding potential or actual nitrosamine contamination" before the July 2018 valsartan recalls. Dkt. 303 ¶ 6. The Manufacturer Defendants intend to give this language its plain meaning: communications that relate to a potential contamination of valsartan with nitrosamines before July 2018. Recognizing that the Court had also arguably defined "potential nitrosamine formation" in paragraph 7 of its order as "documents … regarding unknown or unidentified testing peaks," the Manufacturer Defendants have also agreed to produce communications with foreign regulatory agencies pre-dating July 2018 related to unknown or unidentified peaks in tests capable of detecting nitrosamines, should any exist.

Plaintiffs complain that unidentified peaks in testing capable of detecting nitrosamines might not "be the sole type of 'potential' contamination signal." Dkt. 311 at 26. However, they do not offer any other types of "signals" that might indicate potential nitrosamine contamination. To the extent Plaintiffs believe that some other hypothetical "signal" should have put the Manufacturer Defendants on notice of potential nitrosamine formation, that issue goes to the heart of Plaintiffs' theory of the case. The burden is on Plaintiffs to identify what else should have notified the Manufacturer Defendants of this potential byproduct of the manufacturing process. And Plaintiffs have long possessed the documents necessary for them to consult experts and identify their preliminary theories: over 200,000 pages of core discovery that describe the chemistry behind the manufacturing processes, the types of testing performed, and the FDA's root cause analysis into the alleged impurities.

b) Regulatory Communications Regarding Unapproved, Tentatively Approved or Withdrawn ANDAs

Defendants believe the Court's November 25, 2019 Order already resolved this issue. Pursuant to the Court's Order, regulatory communications regarding the actual or potential presence of nitrosamines prior to July 2018 will be produced. Dkt. 303 ¶¶ 4, 6-7. To the extent such communications exist in relation to unapproved, tentatively approved, or withdrawn ANDAs, the Manufacturer Defendants will produce such communications. As discussed above in response to section 5, ordinary regulatory communications about these ANDAs which do not relate to nitrosamines should not be produced, as such communications do not involve products which have been sold in the United States or were purchased or used by any of the Plaintiffs.

c) Documents Regarding cGMP Compliance

In a December 3rd email, the Court instructed Plaintiffs to "sharpen their pencils" with regard to Request No. 65 as it was facially overbroad. Although Plaintiffs now limit this request to "the valsartan manufacturing process and use or reuse of solvents," they have not meaningfully changed the problematic language: "complete documentation of Defendant's efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs…."[6] This language is so broad and vague that it has almost no meaning. cGMPs permeate all aspects of the pharmaceutical manufacturing process. As written, this request could be construed to seek every document ever created related to the valsartan manufacturing process. In addition, Request No. 65 is duplicative of other requests related to the valsartan manufacturing process and FDA correspondence. The Court should strike this facially improper request in its entirety.

12. Complaints and Recalls (Plaintiffs' Requests Nos. 66-78)

a) Complaint and Recall Documents Relating to both Valsartan API and Valsartan Finished Dose

Plaintiffs state that Defendants have taken the position "Plaintiffs are *only* entitled to responsive documents regarding complaints and recalls related to the Valsartan API (and not finished dose)," but this is incorrect. Defendants will produce responsive documents subject to all of the Court's rulings on the macro discovery issues and based on the parties' finalized agreed-upon lists of search terms and custodians and/or from non-custodial sources and databases where responsive documents are reasonably expected to reside. The Court set the parameters for relevance in its rulings on the macro issues. Regarding finished dose manufacturers, the Court was clear in its Opinion that it "does not expect the discovery . . . produced by the finished dose manufacturers to be as extensive as that produced by the API manufacturers." 11/20/19 Tr. of Oral Ruling at 14:6-

[6] Plaintiffs changed the request from "all documents" to "complete documentation," but there is no apparent difference between the two phrases.

8. The Court went on to say, "Plaintiffs are entitled to discover what steps the finished dose manufacturers took in…regard [to their quality assurance obligation] and whether they knew or should have known about problems with their API suppliers' tests and processes." *Id.* at 15:1-5. Further, the Court said "[a]t a minimum, these facilities must produce API testing results, inspection reports, and communications regarding potential or actual nitrosamine contamination." *Id.* at 15:23-25. Therefore, Defendants believe the Court's November 25, 2019 Order already resolved this issue.

b) Objection for Lack of Possession, Custody, or Control:

This is a valid objection and should not be stricken. The objection was raised wherever Plaintiffs asked for "all" documents without distinguishing between valsartan API and valsartan finished dose. Plaintiffs state that they intended for the definition of "valsartan" to take on a broad meaning in their requests, encompassing both the API as well as the finished product. However, not all Defendants are API manufacturers and, therefore, they likely do not have possession, custody or control of "all" documents regarding valsartan API. For example, Aurolife Pharma LLC ("Aurolife") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") are not API manufacturers. They get their API from Aurobindo Pharma Ltd. Therefore, they objected to the extent Plaintiffs use of "valsartan" was intended to request all documents regarding valsartan API. Nonetheless, they will produce responsive documents that are in their possession, custody or control, subject to the Court's rulings on the macro discovery issues.

c) Communications Made to Physicians:

Defendants do not believe any dispute remains with respect to this section. Defendants objected to Plaintiffs' Request No. 70 as overbroad and not proportional to the needs of the case because it called for production of "all" communications regarding "valsartan due to contamination" whether or not related to a recall. Defendants believe the Court's November 25, 2019 Order already resolved this issue. Subject to this objection and the Court's rulings on core discovery, Defendants will produce responsive documents in their possession, if any, regarding valsartan due to the presence of nitrosamines, which documents Defendants will search for using agreed-upon search terms and custodial files and/or non-custodial data sources.

13. Warranties and Statements (Plaintiffs' Requests Nos. (79-92)

a) Documents Regarding Communications to Investors Related to Manufacturing Processes and Facilities

Plaintiffs have failed to articulate any reasoned basis why non-public communications to investors are relevant to any claims or defenses in this litigation. The examples Plaintiffs provide of statements attributable to executives for the Teva and Mylan Defendants are misrepresented, taken out of context, and in any event do not reflect the types of documents Plaintiffs purportedly seek.

First, the comments cited in Exhibit 10 of plaintiffs' opening brief are from 2013 and were made by the President and CEO of Teva Europe, not the entire company. These publicly-reported

remarks were not found in any communications to investors. Second, the press release cited in Exhibit 11 of plaintiffs' opening brief as "respond[ing] to" these 2013 comments is a letter from 2015 wherein Mylan responded to an attempted acquisition of Mylan by Teva. Simply put, these two articles have nothing to do with each other, do not in fact address or relate to any quality issues pertinent to this litigation, and are not communications to investors. Nothing in these statements supports Plaintiffs' extrapolation that "it is clear some Defendants . . . were engaging in some discussion with investors regarding their foreign manufacturing."

b) Documents and Communications with the NIH and WHO:

Defendants believe the Court's rulings on the macro issues already resolved this issue. The Court's rulings placed clear limits on foreign regulatory discovery. Dkt. 303 ¶¶ 6-7. Defendants objected to Plaintiffs' Request No. 90 to the extent it sought all documents and communications with the World Health Organization ("WHO") and the National Institute of Health ("NIH") because there could be foreign communications and documents exchanged with those organizations that could fall beyond the scope of the Court's rulings on the macro discovery issues. The Court denied Plaintiffs' requests for all foreign discovery, including regulatory documents, sales, marketing materials and agreements. The only exceptions to this carved out by the Court are:

> [R]egulatory inspection reports, warning letters akin to what the FDA sends, 483-like documents, the responses to these documents, root cause analyses regarding the valsartan contamination, and documents regarding potential or actual nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period (Dkt. 303 ¶ 6);
>
> [T]o the extent defendants have possession, custody, or control of documents from any source regarding unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan, the documents shall be produced.

Subject to the Court's rulings, all Defendants will produce responsive documents in their possession, if any exist, which Defendants will search for using agreed-upon search terms and custodial files and/or non-custodial data sources.[7]

14. Sales and Distribution (Request Nos. 93-98)

It's unclear how Plaintiffs narrowed the scope of these requests at all let alone "substantially." Plaintiffs did not amend Requests Nos. 93-95 at all. Defendants agree with Plaintiffs that an interrogatory response may be a reasonable way to respond to these requests subject to the parties and the Court defining the scope of the sales and pricing information at issue. At

[7] This includes Aurolife and Aurobindo USA.

Request No. 96, they simply added the phrase "standard operating" before "procedures." At Request No. 97, they removed the words "documents," "ingredients," and "quality," but they expanded the request to include "bioequivalence." Finally, at Request No. 98, they simply rephrased their request for "all documents relating to" to "complete documentation of the basis for."

a) API Sourcing and due diligence documents

Plaintiffs' state that Defendants "have refused to respond as to whether they will produce documents in response." This is incorrect. The parties met-and-conferred on Wednesday, November 27th. Plaintiffs served amended requests on Friday, November 29th. The parties then corresponded with the Court and the Court provided its thoughts on Plaintiffs amended requests. In response, Plaintiffs advised that they would further modify their amended requests. Defendants asked Plaintiffs to serve the modified amended requests as soon as possible so that the meet-and-confer process could continue. These further modified requests were not served until December 5th, after Plaintiffs filed their Brief. Having reviewed those and the Plaintiffs' Brief, Defendants state as follows:

Request Nos. 96 and 98 – Defendants object to the phrase "due diligence performed (or meant to be performed)" as vague and lacking in particularity. Subject to this objection and the Court's rulings on the macro discovery issues, Defendants who sourced API from unaffiliated companies agree to produce responsive documents in their possession, if any, relating to their decision to purchase valsartan API from other API or finished dose manufacturers, which documents Defendants will search for using agreed-upon search terms and custodial files and/or from databases where responsive documents are reasonably expected to reside.

Request No. 97 – Defendants object to the extent Plaintiffs seek documents beyond the Court's limitation on finished dose discovery insofar as they ask for "all" communications "with regard to the manufacturing process, purity…or contamination relating to valsartan." "In this regard," the Court said, "plaintiffs need to find out if these facilities followed current good manufacturing procedures or practices. Plaintiffs are entitled to find out if these facilities had actual or constructive notice of the contaminated Valsartan API." (Tr. at 14:16-21). Specifically, the Court listed: "API testing results, inspection reports, and communications regarding potential or actual nitrosamine contamination." (Tr. at 15: 23-25). Defendants hereby incorporate their argument regarding the interpretation of "potential contamination" as though set forth at length here. Accordingly, and without waiving the foregoing objection, Defendants agree to produce responsive communications in their possession, if any, with regard to API testing results, inspection reports, and potential or actual nitrosamine contamination, which Defendants will search for using agreed-upon search terms and custodial files and/or from databases where responsive documents are reasonably expected to reside.

15. Valsartan Purchasers, Sales, and Pricing (Request Nos. 99-106)

a) Plaintiffs have refused to narrow their demands for sales and pricing data, leaving the Manufacturer Defendants no choice but to stand on their objections.

The Plaintiffs opening letter brief demonstrates that they have no intention of limiting their document requests for sales and pricing data to information they "genuinely need," as this Court instructed in its December 3, 2019 email to the parties. Instead, the Plaintiffs attempt to argue why their overbroad requests do not need to be refined. These arguments are without merit and should be rejected.

First, the Plaintiffs assert that "production of transactional data is routine in complex class action cases," and that they require this information to establish numerosity, ascertainability, and damages in their economic loss case for purposes of class certification. Nevertheless, Plaintiffs concede – as they must – that the Manufacturer Defendants do not sell valsartan directly to consumers. Thus, the Plaintiffs cannot escape the reality that they are in the best position to determine who purchased valsartan and how much these end-purchasers paid. Moreover, to the extent this information can be obtained from Defendants in this case, the Manufacturer Defendants are not the proper target of such requests.

The Plaintiffs' alternative arguments for why their overbroad requests should be permitted carry even less water. Specifically, the Plaintiffs suggest that claims they have asserted under state law allow recovery of restitution, disgorgement of profits, and unjust enrichment. Rather, the Plaintiffs only potential category of economic loss damages relates to the price that each proposed class member paid out-of-pocket for valsartan prescriptions. Accordingly, the Plaintiffs' potential economic loss damages are narrow and limited, and do not support these expansive, over broad requests.

Perhaps recognizing the limited scope of their economic damages, the Plaintiffs also assert that they need sales and pricing data in order to prove liability. Specifically, the Plaintiffs argue that they are entitled to broad discovery regarding sales and profits because it will help them to determine whether the Manufacturer Defendants were able to sell "contaminated valsartan" at a lower price than "competing non-contaminated" valsartan because they used recycled solvents or otherwise took "short-cuts" that resulted in the creation of nitrosamines. This logic is so strained that it only reinforces the extent to which the Plaintiffs' requests are untethered from the realm of permissible discovery.

While the Manufacturer Defendants acknowledge that certain categories of sales data, such as batch and lot information, is potentially discoverable, Plaintiffs' requests for this information are premature and should be deferred pending class certification. *See* 3 NEWBERG ON CLASS ACTIONS, 9.44 (4th Ed. 2006) (stating, "[i]n a class action for damages, discovery concerning transactions of class members that will form the basis for collective claims for damages may become

unnecessary if class status is denied. Thus, with respect to this area of discovery . . . the courts have found it appropriate to defer such discovery pending the initial class determination."); *Gusman v. Comcast Corp.*, 298 F.R.D. 592, 595 (S.D. Cal. 2014) (noting that merits discovery is usually deferred until a class has been certified and that pre-certification discovery is limited to certification issues including the number of class members, the existence of common questions, typicality of claims, and the representative's ability to represent the class).

Further, the Plaintiffs' discovery requests, as written, are so overbroad and devoid of specificity that the Manufacturer Defendants cannot be reasonably expected to produce documents in response. For instance, the Plaintiffs assert that they need "pricing data fields," but have failed to even attempt to define any field. The same applies to the Plaintiffs' request for the Manufacturer Defendants' profits. Plaintiffs' position is, in effect, that they are entitled to information relating to sales to and profits coming from every entity on a worldwide basis. This is overbroad on its face given that each and every one of the Plaintiffs are from the United States citizens and purchased their VCMs in the United States.

As the Court previously observed, the Plaintiffs must tailor their requests to "give the defendants fair notice of what they should produce." To this end, the parties have continued to meet and confer regarding this issue, however, at the time of filing of this brief, the Parties have not yet reached a final agreement to limit these requests.

16. Available Third-Party Data Sources (Nos. 112-113)

a) Commercially Available Data

Following further discussion and analysis, the Manufacturer Defendants represent that they will produce responsive, non-privileged documents maintained in the ordinary course of business during the relevant time period for each Defendant as defined by the Court.

b) Copay/Coupon Related Documents

Defendants' response to this request may be impacted by the Court's resolution of the question of discovery into sales and pricing information. To the extent coupon or co-pay information relates to discoverable sales and pricing information, the Manufacturer Defendants will produce responsive, non-privileged documents maintained in the ordinary course of business during the relevant time period for each Defendant as defined by the Court. This response is not limited to custodial or non-custodial files.

17. Defendant-Specific Requests

Defendants agree that no outstanding disputes remain with respect to the Defendant-specific requests.

II. Custodians

1. The ZHP Defendants

Plaintiffs appear to be satisfied with between 25 and 35 custodians for each of the other Manufacturer Defendants. Through the various meet and confers, including the all-day meeting with Mr. Du in Court, ZHP has identified the 42 employees among the various ZHP parties as having the critical information pertaining to valsartan-related manufacturing, quality assurance and control (which includes testing), research and development, sales, and regulatory affairs. ZHP has also offered to add another eight custodians of Plaintiffs' choosing, for a total of 50 custodians.[8] Underscoring the reasonableness of ZHP's proposed 50-custodian limit, is *Plaintiffs' own agreement* that the Torrent parties should agree to a 25-custodian cap while those parties complete their custodian meet and confers. Nevertheless, Plaintiffs insist on ***123 custodians*** from ZHP.[9] The only plausible conclusion from these inconsistent approaches is that Plaintiffs—perhaps recognizing the burden and cost of litigating against a Chinese defendant—are using discovery as a litigation tactic in an attempt to coerce ZHP into settlement. Using discovery as an adversarial tool "is anathema to the principles underlying the Federal Rules." *Webasto Thermo & Comfort North America, Inc., v. BesTop, Inc.*, 326 F.R.D. 465, 469 (E.D. Mich. 2018). The Court should endorse ZHP's proposed custodian list, or provide Plaintiffs with up to 50 ZHP custodians of their choosing.[10]

Indeed, more than ***64 million pages*** of documents were produced in *In re: Benicar (Olmesartan) Prods. Liab. Litig.*, No. 14-2606, 2016 WL 5817262, at *1 (D.N.J. Oct. 4, 2016), where there were approximately 160 custodians. Were that amount of information produced here, ZHP would be forced to pay $42 million just to have a machine translate the documents at the going rate of $0.67 per page. 100 document reviewers working 50-hour weeks would need approximately 5 years to review that information. Thus, the burden of collecting, reviewing and producing information from 123 custodians versus from 42 is demonstrably different. On top of those costs,

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[8] In addition to the 50 custodians, ZHP has proposed two custodians related to the Xunqiao valsartan finished dose facility, and is still in the process of determining whether any others have had meaningful involvement with the limited valsartan-related finished dose issues pertinent here. In addition to the Xunqiao custodians, ZHP has already proposed as custodians employees at its subsidiaries that handle research and development, sales, and regulatory affairs activities for valsartan finished dose.

[9] Plaintiffs attempt to justify their list by pointing out that it applies to six separate companies. However, the purpose of the custodian lists is to identify the employees likely to have the pertinent information, within the bounds of proportionality. ZHP's list of 42, which includes employees of all six ZHP related companies, satisfies this standard.

[10] ZHP does not categorically oppose including Jun Du as a custodian. However, as a senior executive, he does not possess the same quality of manufacturing-related information as the custodians ZHP has proposed.

ZHP will bear the extra burden of reviewing documents in accordance with Chinese law. *See* Law on Guarding State Secrets of the People's Republic of China 1988 as revised in 2010, Order No. 6 of the President of the People's Republic of China. Where the 42 custodians ZHP has proposed will cover the waterfront on responsive information, granting Plaintiffs' request for 123 custodians, especially on the threadbare rationale that the additional custodians work for the ZHP parties, would make discovery punitive.

Slicing through Plaintiffs' rhetoric about the meet and confer process reveals just two bases Plaintiffs have offered for their list of 123 custodians. Plaintiffs assert that, (i) unlike in *Benicar*, they have not received a "substantial volume of relevant documents" from which to identify custodians; and (ii) ZHP has not provided "a robust, substantive explanation establishing why each" of Plaintiffs' additional 88 custodians "is not needed." However, these reasons do not satisfy Plaintiffs' burden—and it is *Plaintiffs' burden*, *see* Dkt. 312 at 6-7 (collecting cases)—of demonstrating why ZHP's custodian list is inadequate, nor do these bases support an ESI custodian list approximately ***four times as many*** as for any of the other Defendants.

Accepting Plaintiffs' assertion that a "substantial volume" of documents was necessary to establish the custodian list in *Benicar*, that case is thus supportive of ZHP's position that the ZHP custodian list should be limited to 50 or fewer. Here, ZHP has already produced the documents at the very core of the claims at issue, and it is ***undisputed*** that the custodians ZHP has proposed are reflected throughout those documents as having meaningful involvement with the historical and recent manufacturing, quality assurance/control, R&D, sales, and regulatory facts at issue. Should the production of additional documents show cause for adding custodians above the 50 that ZHP has proposed, Plaintiffs may make that application; as they did in *Benicar*, and as is customary and required under the applicable case law. *See* Dkt. 312 at 6-7 (collecting cases).

Plaintiffs' suggestion that ZHP should have incurred the expense of a "robust, substantive explanation," as to each of the 88 additional custodians they proposed, which list has been a moving target since their first letter identifying 149 custodians in mid-November, turns the burden of selecting ESI custodians on its head. Indeed, Plaintiffs have gone so far as to suggest that a custodian would only be duplicative or cumulative if ZHP could demonstrate that 100% of one of the proposed custodian's email was identical to 100% of another custodian's email. This cannot be, and, in fact, is not the standard. "Absent agreement among the parties, the party who will be responding to discovery requests is entitled to select the custodians it deems 'most likely to possess responsive information and to search the files of those individuals.'" *In re EpiPen Marketing, Sales Practices and Antitrust Litigation*, MDL No. 2785, 2018 WL 1440923, at *2 (D. Kan. Mar. 15 2018) (quoting, *inter alia*, *Firefighters' Ret. Sys. v. Citco Grp. Ltd.*, No. 13-373, 2018 WL 276941, at *4 (M.D. La. Jan. 3, 2018)).

Plaintiffs claim that they have "limited information" about ZHP's employees and that ZHP has "provided the bare minimum of information," Dkt. 311 at 40, but they make no mention of the detailed information provided in ZHP's November 27 letter, and they never articulate what information they are missing. Nor can Plaintiffs claim that any other Manufacturer Defendant has

provided them with more information than ZHP because, after all, ZHP is the only company that had a corporate representative meet with Plaintiffs *for an entire day* to answer questions about internal company structure and employees.[11]

Moreover, Plaintiffs have no legal basis to oppose ZHP's proposal of a 50-custodian limit, especially given that it is without prejudice to their seeking to add additional custodians later for cause. While Plaintiffs' claim that limit is arbitrary, Plaintiffs' themselves agree that a 25-custodian cap is appropriate and helpful for the Torrent Defendants, and courts routinely impose limitations on the number of custodians as an effective and practical way of resolving disputes about custodian lists. *See, e.g., Cannata v. Wyndham Worldwide Corp.*, No. 10-00068, 2011 WL 5598306, at *3 (D. Nev. Nov. 17, 2011) ("The plaintiffs shall limit their ESI requests to a total of 20 custodians…."); *Martinelli v. Johnson & Johnson*, No. 15-01733, 2016 WL 1458109, at *1 (E.D. Cal. Apr. 13, 2016) (requiring the parties to propose "list[s] of twelve (12) most likely custodians" and ruling that "[a]bsent a showing of good cause, and subject to any further agreement among the parties, the list(s) provided pursuant to this paragraph shall be the presumptive limit on permissible ESI discovery.").[12]

For these reasons, and those discussed in the Manufacturing Defendants' opening brief, ZHP respectfully requests the Court issue an Order endorsing ZHP's proposed list of 42 custodians or, in the alternative, providing Plaintiffs with up to 50 ZHP custodians of their choosing.

2. The Teva Defendants

The Teva Defendants continue to collect information on certain custodians proposed by Plaintiffs. During a meet and confer on December 10, 2019, the Teva Defendants agreed to add 2 additional custodians, bringing the total number of custodians to 34. The parties continue to try and finalize the custodian list in advance of the December 11, 2019 Case Management Conference, and

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[11] Plaintiffs' hand-waving about the translation of organizational charts is unnecessary. They received new fully translated versions of the Chuannan facility API organizational charts immediately upon notifying ZHP's counsel that the original translations were incomplete, and, although they never requested translated organizational charts for the Xunqiao finished dose facility, those were produced on December 8.

[12] *See also Fleming v. Cobra Electronics Corp.*, No. 12-392, 2012 WL 10243649, at *2 (D. Id. Nov. 9, 2012) ("Each requesting party shall limit its email production requests to a total of five custodians per producing party for all such requests."); *Natural Alternatives Int'l, Inc. v. Hi-Tech Pharmaceuticals, Inc.*, No. 16-02343, 2017 WL 3668738, at *2 (S.D. Cal. May 8, 2017) ("Each requesting party must limit its email production requests to a total of ten custodians per producing party."); *Stinson v. City of New York*, No. 10-4228, 2015 WL 4610422, at *4 (S.D.N.Y. July 23, 2015) ("As to the three categories that contemplate an indefinite amount of custodians … each category contains its own limiting principle, but the parties are directed to meet and confer in order to develop a specific list of custodians to search, not to exceed 25 in total.").

the Teva Defendants anticipate the parties will reach agreement on the custodian list by December 18, 2019, at the latest.

3. The Torrent Defendants

Torrent maintains that the current agreed-upon list of 18 custodians is sufficient to ensure that plaintiffs receive relevant information. However, Torrent will agree to plaintiffs' request for a cap of 25 custodians and will add up to 7 more custodians upon a showing of good cause. Torrent is continuing to gather additional information and will continue to meet and confer with plaintiffs with the goal of finalizing the custodian list by December 18.

4. Aurolife Pharma LLC and Aurobindo Pharma USA, Inc.

Aurolife and Aurobindo USA continue to collect information on the four individuals raised in Plaintiffs' Brief and have scheduled a meet and confer for December 10, 2019, to try and finalize the custodian list in advance of the December 11, 2019 Case Management Conference. Aurolife and Aurobindo USA anticipate the parties will reach agreement on the custodian list by December 18, 2019, at the latest.

5. Mylan Pharmaceuticals Inc.

Mylan and the Plaintiffs have agreed to a final list of 33 API manufacturing custodians. With respect to finished dose custodians, the parties will continue to meet and confer regarding those individuals who may possess information regarding the finished dose functions that the Court has deemed to be potentially relevant to this case. Mylan anticipates that the parties will reach agreement on a final list of finished dose custodian on or before December 18, 2019.

III. Search Terms

Based upon the Court's suggestion and guidance, the parties have met and conferred further and have resolved three out of the four categories of documents in dispute, as detailed below. The only remaining category in dispute relates to the 17 terms objected to by Defendants on the Plaintiffs' proposed cGMP primary terms list.

1. Resolved Issues

Plaintiffs believe that their primary search terms and modifiers categories and suggested search combinations are proper. Defendants believe that many of these terms and modifiers, as proposed, will require substantial unnecessary efforts and cost. The Parties continue to be willing to refine and narrow these search terms in order to reduce unnecessary efforts and cost while also minimizing the risk that relevant documents will be excluded and therefore not be reviewed for responsiveness to Plaintiffs' document requests. To that end, the Parties have devised and agreed upon the detailed method described below for further evaluating disputed search terms while simultaneously reviewing and producing non-custodial documents and documents resulting from

undisputed search terms. The Parties respectfully submit that this procedure will allow for the most expeditious rolling production of documents by Defendants while giving the Parties the ability to further refine the search terms as necessary based upon actually collected documents and data.

A. Standalone Terms

a) The following terms shall remain on the standalone terms list but can be tested and refined further if a need is shown after documents are collected and preliminarily reviewed:

i. *diethylamine or "*diethyl amine"
ii. *dimethylamine or "*dimethyl amine"
iii. *dimethylformamide or DMF
iv. *dimethylmethanamide
v. *ghost*
vi. *NDEA*
vii. *NDMA*
viii. *nitra*
ix. *nitrite*
x. *nitrosa*
xi. *nitroso*
xii. *trosomine*
xiii. C2H6N2O or "(CH3)2NN=O" or "CH32NN=O" or "(CH3)2NC(O)H" or CH32NCOH or C3H7NO or "(CH3CH2)2NH" or CH3CH22NH or C4H11N or "(CH3)2NH" or CH32NH or C2H7N or "(C2H5)2NNO" or C2H52NNO or C4H10N2O
xiv. tetrazol*
xv. gene* /3 mutat*
xvi. genotoxic*
xvii. carcin* (but may modify if needed)
xviii. deviat* /5 cancer* or deviat* /5 toxic or deviat* /5 hazard* or deviat* /5 fatal (but may modify if needed)
xix. FDA /10 warning (but may modify if needed)
xx. solvent /5 cancer* or solvent /5 toxic or solvent /5 hazard* or solvent /5 fatal (but may modify if needed)
xxi. solvent* /5 contamin* (but may modify if needed)
xxii. Valisure* (but may modify if Valisure comes up for a reason other than its role in relation to detecting nitrosamines).

b) The following terms (1) when used against data of custodians working only at a particular facility would be run as standalone terms; and (2) when used against data of custodians in management over more than one facility would be run with <term> AND (<Drug Name> OR <Solvents> OR <Facility Name>), but can be tested and

refined further to be <term> AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) if needed:

i. EIR or "establishment inspection report"
ii. OAI or "official action indicated"
iii. "voluntary action indicated"
iv. (Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn*) or (704 pre/3 b)

c) The following terms shall be moved to the Manufacturing primary terms list:

i. diastereo*
ii. moiety or moieties
iii. *formaldehyde*

d) The term "test* /5 canc*" can be run as follows: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))

e) The inclusion or modification of NMBA will be decided after the JPML's decision on expansion of the MDL.

B. Manufacturing, Medical Conditions, Economic Terms, Entities

a) The search string for these primary terms categories will be changed to: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) where <other drug names> will be an agreed to list of the names of each other non-valsartan (or other sartan depending on the JPML's ruling) drug manufactured by the defendant running the modifiers;

b) Plaintiffs will identify a subset of these terms that they believe need to run with <Term> AND (<Drug Name> OR <Solvents>) instead (i.e. without excluding other drug names), which will be subject to testing and sampling as to the differential results;

c) Any terms still in dispute after such testing, sampling, and meet and confers will be promptly brought to the Court for resolution.

C. QA-Testing, cGMP (two undisputed terms), and Regulatory

a) The search string for these will be changed to: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))or [other categories of modifiers]);

b) The Parties will negotiate any further modifications in either direction (e.g. narrowing or broadening), if needed, once documents have been collected and initially reviewed.

c) Any terms still in dispute after such testing, sampling, and meet and confers will be promptly brought to the Court for resolution.

D. 31 Terms Completely Objected to by Defendants

a) Defendants will run hit counts using the search string agreed upon for each particular term for those terms Defendants objected to as "overly generic terms" or "overly generic terms in light of defendants' business";

b) The hit counts will be reviewed, documents sampled if necessary, and the Parties will meet and confer on how to narrow the terms if needed;

c) If the Parties cannot agree, they will promptly bring the issue to the Court for resolution.

Thus, at this time, the Parties do not require the Court's intervention with regard to the above categories of search terms. As detailed above, if the Parties cannot agree on any remaining disputes once documents have been collected and a preliminary review has been conducted, the Parties will promptly, and the extent practicable, jointly bring the issue before the Court for resolution.

IV. Plaintiffs' Request for an Order Compelling Another Meet and Confer Regarding Defense Information Re: ESI and Physical Document Storage Should be Denied

Relegated to the last few pages of their extensive brief is another attempt by Plaintiffs to burden corporate representatives of the Manufacturer Defendants with an in-person interview about ESI and physical document storage. However, Defendants have provided or have agreed to follow up with all of the information Plaintiffs requested on November 11th regarding ESI and physical document storage and have thus discharged their obligations under the controlling authorities.

Sedona Principle 6 provides: "Responding parties are best situated to evaluate the procedures, methodologies, and technologies appropriate for preserving and producing their own electronically stored information." The Sedona Principles, Third Edition: Best Practices, Recommendations & Principles for Addressing Electronic Document Production, 19 Sedona Conf. J. 118 (2018) (quoted in *Enslin v. Coca-Cola Co.*, No. 14-06476, 2016 U.S. Dist. LEXIS 193556, at *2 (E.D. Pa. June 8, 2016); *see also Ford Motor Co. v. Edgewood Props., Inc.*, 257 F.R.D. 418, 427 (D.N.J. 2009) ("The Sedona Principles wisely state that it is, in fact, the producing party who is [in] the best position to determine the method by which they will collect documents. . . . [A]bsent an agreement or timely objection, the choice is clearly within the producing party's sound discretion.").

Plaintiffs' request is tantamount to a 30(b)(6) deposition and Principle 6 eschews such "discovery on discovery." *Id.* at 118. Indeed, Comment 6.a. to Principle 6 explains that "the case law and the procedural court rules provide that discovery should take place without court intervention, with each party fulfilling its discovery obligations without direction from the court or opposing counsel." *Id.* at 118 (listing rules and cases). "Those discovery obligations also include the duty to use reasonable efforts to locate and produce ESI responsive to the opposing party's requests and within the scope of discovery." *Id.* at 119.

Here, Plaintiffs have made their discovery requests, the Court has or will rule on their scope, and the Manufacturer Defendants will then collect and produce responsive information. There is no need for any court intervention. This is especially true because, as explained below, each of the Manufacturer Defendants has not only met and conferred, but also provided, or agreed to follow-up and later provide, all requested information regarding ESI and physical document storage. Although not every Manufacturer Defendant has relayed follow-up information yet, every one of them intends to do so as soon as practicable.[13]

Although Plaintiffs directed their argument generally at all of the Manufacturer Defendants, each of the Manufacturer Defendants provides a specific response below.

2. The ZHP Defendants

The ZHP Defendants participated in an interview with Plaintiffs on November 15, 2019 in Philadelphia. For more than two and a half hours, ZHP's counsel answered questions from Plaintiffs' counsel and ESI consultant about the topics raised in Plaintiffs' narrowed November 11, 2019 letter. Defendants' counsel also answered questions that were not included in the November 11, 2019 letter. Defendants' counsel even agreed to follow up with Plaintiffs' counsel after obtaining answers to multiple questions that were not raised in the November 11, 2019 letter. Defendants' counsel did not refuse to answer any question posed during the meet and confer.

In preparation for the meeting with Plaintiffs on November 15 at 2:00 p.m., Defendants' counsel spoke for multiple hours with the head of Information Technology for ZHP, Yong Zhou, and the head of Information Technology for Prinston, Solco, and Huahai US, Nelson Liu. Those custodians were not available to attend the interview – and Plaintiffs' counsel did not object to their unavailability – because it was 3:00 am in China for Mr. Zhou and because Mr. Liu was on a plane that day flying to China for a vacation. Plaintiffs did not request that ZHP's counsel call any other

[13] It is worth noting that Plaintiffs failed to comply with L.Civ.R. 37.1(a)(1). The first time any of the Manufacturing Defendants learned that Plaintiffs were unsatisfied with the outcome of the various meet and confers was Plaintiffs' opening brief. Plaintiffs are asking the Court to order another meet and confer with each Manufacturer Defendant before even asking any of the Manufacturer Defendants for another meet and confer and before even alerting the Manufacturer Defendants of any dissatisfaction with the information provided.

employees during the meet and confer, or that ZHP's counsel arrange a follow-up call or meeting with Mr. Zhou or Mr. Liu.

ZHP's counsel is still collecting information from multiple sources and expects to respond to Plaintiffs' outstanding questions this week.

3. Mylan Pharmaceuticals Inc.

Along with several of the other Manufacturer Defendants, Mylan participated in an interview with Plaintiffs on November 15, 2019 in Philadelphia. Unlike the other Manufacturer Defendants, however, Mylan brought a company representative to the meeting. Thus, while all the Manufacturer Defendants participated in the Court-mandated interview in good faith, Mylan more than satisfied its obligation by providing the Plaintiffs' counsel – and the Plaintiffs' technical consultant, Mr. Jaffe – with unfettered access to a knowledgeable Mylan employee for two hours (which was the maximum amount of time that Plaintiffs' schedule allowed).

In their letter brief, the Plaintiffs acknowledge that Mylan was the only Defendant who brought a company employee to the interview. Nevertheless, the Plaintiffs now assert—for the first time— that Mylan failed to bring the appropriate "company representative" to the meeting because the company representative is a member of Mylan's in-house legal department. The Plaintiffs' assertion is nothing more than gamesmanship and should be rejected by this Court for two reasons.

First, this Court's November 7th Order required the Manufacturer Defendants to provide the a "***person or persons with knowledge*** about the client's information management systems, including computer-based and other digital systems, with the ability to facilitate, through counsel, reasonably anticipated discovery." (ECF No. 292 (emphasis added).) Pursuant to the Order's unambiguous directive, the Manufacturer Defendants were not required to make an information technology professional available. Moreover, because a significant number of the Plaintiffs' questions related to legal holds and document retention policies, the Plaintiffs cannot reasonably assert that an in-house lawyer is not a "person with knowledge" regarding these issues.

Second, neither at the conclusion of the November 15th interview, nor at any time thereafter, did the Plaintiffs indicate that Mylan had failed to produce an appropriate company representative or provide adequate information. Likewise, the Plaintiffs never suggested that a second in-person conference with Mylan might be necessary, let alone alert Mylan that the Plaintiffs intended to petition the Court for a second interview. Most tellingly, Plaintiffs have failed to direct the Court to any information that Mylan failed to provide at the meeting. Rather, all of Plaintiffs' allegations regarding the failure to provide information at the interview are generalized as to all Manufacturer Defendants. As far as Mylan is aware, the only outstanding questions from the interview relate to hyper-technical requests for information that went beyond the generalized discussion topics outlined by Plaintiffs in advance of the meeting.

Mylan produced a company representative for a two-hour interview with the Plaintiffs, during which Mylan provided substantive information pertaining to the topics outlined by the

Plaintiffs in advance of the meeting. Plaintiffs never so much as hinted that Mylan's efforts were insufficient until their December 5th letter brief. Contrary to the Plaintiffs' specious assertions, Mylan has fully complied with this Court's November 7th Order. As a result, Plaintiffs' unwarranted and unreasonable request for a second interview with a Mylan company representative should be denied.

4. Aurolife Pharma LLC and Aurobino Pharma USA, Inc.

Aurolife and Aurobindo USA continue to collect information regarding ESI and Physical Document Storage requested by Plaintiffs and will continue to provide information to Plaintiffs prior to the December 11, 2019 Case Management Conference. To date, defense counsel has provided information to Plaintiffs twice in writing and during three meet-and-confers. Defense counsel was prepared to meet with Plaintiffs' counsel in-person on November 15, 2019 with a representative from Aurobindo USA's IT Department to discuss ESI and physical document storage. On November 11, Defense counsel emailed Plaintiffs' counsel regarding her availability on November 15. On November 13, Plaintiffs' counsel proposed a telephonic meet-and-confer. That same day, Defendants emailed Plaintiffs' a letter providing information responsive to their requests in a good faith effort to obviate the need for a meet-and-confer. That letter was sent as a follow up to Defendants' initial response to Plaintiffs' April 2019 letter and in response to Plaintiff's letter dated November 11, 2019. In response, Plaintiffs said they had additional follow up questions, so the parties proceeded with the telephonic meet-and-confer on November 18.

Many of the questions Plaintiffs include in their Brief were in fact answered by defense counsel for Aurolife and Aurobindo USA in her written correspondence and during the meet-and-confers. Notably, many of the questions posed were not raised in either Plaintiffs' April 2019 letter or their November 11 letter. The fact that further follow up and investigation is needed to answer additional questions raised for the first time on November 18, is not an appropriate basis for ordering a meeting and requiring the presence of a company representative. The parties are fully capable of exchanging this information – to the extent it is actually relevant or necessary – without the Court's involvement at this time.

5. The Torrent Defendants

The Torrent Defendants provided much of the ESI requested by Plaintiffs during a meet and confer on October 9, 2019. In addition, the Torrent Defendants participated in a November 15, 2019 meet and confer with Plaintiffs' counsel to discuss ESI and document storage issues. In preparation for the November 15th meet and confer, counsel spoke with numerous individuals in the Torrent Defendants' Information Technology and Legal Departments in both the US and India.

Over the course of the November 15th meeting, counsel for Torrent answered follow-up questions regarding the information that was previously provided to counsel. During that same meeting, Plaintiffs asked many questions beyond the scope of their November 11 letter. In response

to these new questions, counsel for Torrent is compiling information from various sources and expect to provide an update to Plaintiffs by December 18th.

6. The Teva Defendants

The Teva Defendants participated in a November 15, 2019 meeting to discuss ESI and physical document storage. For more than two hours, Defense counsel answered questions from Plaintiffs' counsel about these topics. In preparation for these meetings, counsel spoke with numerous individuals in the Teva Defendants' Information Technology and Legal Departments, as well as Teva's vendor who handles document collection, review, and production. Representatives for the vendor were available by phone during the meeting to answer any questions Plaintiffs' counsel had related to the vendor's capabilities. Plaintiffs did not pose any questions to the vendor.

Plaintiffs' brief raises highly generalized complaints about the adequacy of these meetings as to the Defendants as a whole. Many of the questions Plaintiffs include in their brief were in fact answered by Defense counsel for the Teva Defendants' during their meeting, and to the extent counsel was unable to provide certain responses, it is notable that many of the questions posed were not raised in either Plaintiffs' April 2019 letter or the more specific letter sent on November 11, 2019. Defense counsel was prepared at the meeting to respond to the items included in the November 11, 2019 letter, and the fact that further follow up and investigation is needed to answer new questions raised for the first time on November 15, 2019 is not an appropriate basis for ordering another meeting and requiring the presence of a company representative. The Teva Defendants have collected further information on a number of topics identified for follow up during the meeting, and anticipate providing an update to Plaintiffs on these items by December 18, 2019. The parties are fully capable of exchanging this information – to the extent it is actually relevant or necessary – without the Court's involvement at this time.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)